

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

**CERTIFICATION OF SETH  
A. GOLDBERG, ESQ.**

SETH A. GOLDBERG, ESQ., being of full age, certifies as follows:

1. I am a Partner at Duane Morris LLP, attorneys for Defendants Zhejiang Huahai Pharmaceutical Co, Ltd., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC. I am also Liaison Counsel for all Defendants in this MDL. I make this Certification based on personal knowledge and in support of the Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Preclude Opinions of Defense Expert George E. Johnson, Ph.D.

2. Attached hereto as Exhibit A is a true and correct copy of Defendants' Rule 26 Disclosure of Expert Witnesses for General Causation, served August 2, 2021.

3. Attached hereto as Exhibit B is a true and correct copy of the FDA's Nitrosamine Workshop – Report Final (July 20, 2021).

4. Attached hereto as Exhibit C is a true and correct copy of Johnson GE, Dobo K, Gollapudi B, Harvey J, Kenny J, Kenyon M, Lynch A, Minocherhomji S,

Nicolette J, Thybaud V, Wheeldon R, Zeller A, *Permitted daily exposure limits for noteworthy N-nitrosamines*, ENVIRON. MOL. MUTAGEN. 62(5):293-305 (2021).

5. Attached hereto as Exhibit D is a true and correct copy of Peto, R et al., *Effects on 4080 Rats of Chronic Ingestion of Nitrosodiethylamine or N-Nitrosodimethylamine: A detailed dose response study*, CANCER RESEARCH 51:6415-6451 (1991).

6. Attached hereto as Exhibit E is a true and correct copy of Macgregor, James T, et al., *IWGT report on quantitative approaches to genotoxicity risk assessment I. Methods and metrics for defining exposure–response relationships and points of departure (PoDs)*, MUTATION RESEARCH, 783:55-65 (2015).

7. Attached hereto as Exhibit F is a true and correct copy of G.E. Johnson, et al., *Derivation of Point of Departure (PoD) Estimates in Genetic Toxicology Studies and Their Potential Applications in Risk Assessment*, ENVIRON. MOL. MUTAGEN. 55:609-623 (2014).

8. Attached hereto as Exhibit G is a true and correct copy of ICH M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (March 2017).

9. Attached hereto as Exhibit H is a true and correct copy of the FDA's M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk (March 2018).

10. Attached hereto as Exhibit I is a true and accurate copy of the transcript of the deposition of George E. Johnson, Ph.D., in MDL 2875, dated October 5, 2021, with errata.

11. Attached hereto as Exhibit J is a true and correct copy of the Expert Report of George E. Johnson, Ph.D., dated August 2, 2021, served in MDL 2875.

12. Attached hereto as Exhibit K is a true and correct copy of Marco J. Zeilmaker, Martine I. Bakker, Ronald Schothorst, Wout Slob, *Risk Assessment of N-nitrosodimethylamine Formed Endogenously after Fish-with-Vegetable Meals*, TOXICOLOGICAL SCIENCES, Volume 116, Issue 1, Pages 323–335 (2010).

13. Attached hereto as Exhibit L is a true and correct copy of Dr. George Johnson's CV, Exh. A to the Expert Report of George E. Johnson, Ph.D., dated August 2, 2021, served in MDL 2875.

14. Attached hereto as Exhibit M is a true and accurate copy of the transcript of the deposition of George E. Johnson, Ph.D., in MDL 2875, dated October 4, 2021.

15. Attached hereto as Exhibit N is a true and correct copy of Jenkins GJ, Doak SH, Johnson GE, Quick E, Waters EM, Parry JM., *Do dose response thresholds exist for genotoxic alkylating agents?*, MUTAGENESIS 20(6):389-398 (2005).

16. Attached hereto as Exhibit O is a true and correct copy of Müller L, Gocke E, Lavé T, Pfister T., *Ethyl methanesulfonate toxicity in Viracept--A comprehensive human risk assessment based on threshold data for genotoxicity*, TOXICOL. LETT. 190(3):317-329 (2009).

17. Attached hereto as Exhibit P is a true and correct copy of White, P.A., et al., *Quantitative Interpretation of Genetic Toxicity Dose-Response Data for Risk Assessment and Regulatory Decision-Making: Current Status and Emerging Priorities*, ENVIRONMENTAL AND MOLECULAR MUTAGENESIS 61:66-83 (2020).

18. Attached hereto as Exhibit Q is a true and correct copy of National Center for Health Statistics, “Anthropometric Reference Data for Children and Adults: United States, 2015–2018” (January 2021).

Respectfully submitted,

/s/ Seth A. Goldberg

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